UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,043	01/02/2004	Syed F.A. Hossainy	50623.362	1927

7590 09/19/2007

Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
GEORGE, KONATA M	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/751,043	HOSSAINY ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-43,46 and 48-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-43,46 and 48-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 37-44, 46 and 48-52 are pending in this application.

Action Summary

1. The examiner acknowledges the cancellation of claims 45 and 47. Therefore, any and all objections and/or rejections directed to them are hereby withdrawn.

2. The rejection of claim 40 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn in view of applicant amendment to the claims.

3. The rejection of claims 37-39, 41-44, 46 and 48-52 under 35 U.S.C. 102(e) as being anticipated by Ding is being maintained for the reasons stated in the office action dated March 30, 2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 37-39, 41-44, 46 and 48-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Ding (US 6,652,581).

Ding discloses a method of curing a composition onto a device (col. 5, lines 5-18). The method evaporates the solvent by heating at approximately 90°C or as high as 150°C (depending on the polymer, drug and solvents used). Column 3, lines 19-20 teach the device including self-expanding stents and balloon expandable stents; lines 33-35 teach the device can be made from polymeric, ceramic, metallic or composite materials. Column 4, lines 1-26 teach examples of the polymers that can be employed in the composition. Column 7, lines 1-21 teach the use of drugs in the composition.

Response to Arguments

5. Applicant's arguments filed July 2, 2007 have been fully considered but they are not persuasive.

Applicant argues that Ding does not teach that the temperature is greater than about the glass transition temperature of the polymer but below the melting temperature of the polymer. The examiner disagrees. As mentioned above, the composition is heated to a temperature from about 90-150°C (depending on the polymer, drug and solvents used). Column 4, lines 1-26 teach polymers that can be used in the composition. It is the position of the examiner that the limitation of the temperature is met by some of the polymers listed, for example, polyvinyl chloride has a glass

transition temperature of 87°C and a melting point temperature of 212°C; polystyrene has a glass transition temperature of 95°C and a melting point temperature of 240°C. As it can be seen from these two examples, the temperature of Ding is above the glass transition temperature and below the melting point temperature.

6. **The rejection of claims 37-44, 46 and 48-52 under 35 U.S.C. 103(a) as being unpatentable over Ding is being maintained for the reasons stated in the office action dated March 30, 2007.**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 37-44, 46 and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding (US 6,652,581).

Applicant claims a method of forming a coating for an implantable device comprising applying a composition including a solvent and a polymer to the device, heating the composition to a temperature that is greater than about the glass transition temperature of the polymer but below the melting temperature of the polymer.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Ding discloses a method of curing a composition onto a device (col. 5, lines 5-18). The method evaporates the solvent by heating at approximately 90°C or as high as 150°C (depending on the polymer, drug and solvents used). Column 3, lines 19-20 teach the device including self-expanding stents and balloon expandable stents; lines 33-35 teach the device can be made form polymeric, ceramic, metallic or composite materials. Column 4, lines 1-26 teach examples of the polymers that can be employed in the composition. Column 7, lines 1-21 teach the use of drugs in the composition.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Ding does not teach that the polymer and solvent composition is drug free.

Finding of prima facie obviousness

***Rational and Motivation* (MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the composition without the use of a drug. It would have been within reason for one of ordinary skill not to add a drug to the coating formulation for the purposes of coating a device (i.e. stent or balloon expandable stents) whose primary purpose is to open the blood vessel and/or keep the blood vessel open, and where drug delivery is not necessary.

Response to Arguments

8. Applicant's arguments filed July 2, 2007 have been fully considered but they are not persuasive.

Applicant argues that Ding does not teach that the temperature is greater than about the glass transition temperature of the polymer but below the melting temperature of the polymer. The examiner disagrees. As mentioned above, the composition is heated to a temperature from about 90 to 150°C (depending on the polymer, drug and solvents used). Column 4, lines 1-26 teach polymers that can be used in the composition. It is the position of the examiner that the limitation of the temperature is met by some of the polymers listed, for example, polyvinyl chloride has a glass transition temperature of 87°C and a melting point temperature of 212°C; polystyrene has a glass transition temperature of 95°C and a melting point temperature of 240°C.

As you can see from these two examples, the temperature of Ding is above the glass transition temperature and below the melting point temperature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 37-43, 46 and 48-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants use the phrase "greater than about" or "above about" in the claims when describing the temperature. It is unclear to the examiner if it is "greater than", "above" or "about" are the intended values.

Information Disclosure Statement

10. The information disclosure statement (IDS) submitted on December 6, 2005 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Conclusion

11. Claims 37-44, 46 and 48-52 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Art Unit 1616

Johann R. Richter
Supervisory Patent Examiner
Art Unit 1616